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5-Fluorouracil and mitomycin-C in colorectal cancer: Unacceptable conclusion

In their paper published in *Annals of Oncology* [1], Ross et al. describe an advantage of the combination of mitomycin-C and protracted venous infusion (PVI) of 5-fluorouracil as compared to PVI-5-fluorouracil alone in the treatment of advanced colorectal cancer. From the data presented, their conclusion is inadequate for the following reasons:

Because of mitomycin-C associated toxicities, the dose of mitomycin-C has been reduced from 10 mg/m² to 7 mg/m² in June 1995. Although I could not find the exact number of patients treated with the lower dose or the higher dose, it appears that about half of the patients in this treatment arm received the lower dose. Response rate in patients receiving higher dose of mitomycin-C was higher (61%) than the response rate of patients receiving lower dose (55%). Due to the toxicities seen, authors recommend treatment with the lower dose of mitomycin-C. However, their conclusion regarding the effect of treatment includes data from patients having received higher dose. Therefore, it can not be concluded that 5-FU and mitomycin-C at lower dose is superior to 5-FU alone.

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Reference

1. Ross P, Norman A, Cunningham D et al. A prospective randomised trial of protracted venous infusion 5-fluorouracil with or without mitomycin C in advanced colorectal cancer. *Ann Oncol* 1997; 8 (10): 995–1001.

This letter was referred to the authors who respond as follows:

The study which we reported in the October 1997 edition of *Annals of Oncology* was designed as part of a stratified study

with oesophago-gastric cancer. The study was designed to detect an improvement in response rates from 35% to 50% with 170 patients per arm providing at least 80% power (α error = 5%). The number of patients with colorectal cancer randomised was increased to 100 per arm to ensure adequate power as a separate study. We observed a significant improvement in response rate from 38% with protracted venous infusion (PVI) 5-fluorouracil (5-FU) alone to 54% with PVI 5-FU plus mitomycin-C ($P = 0.024$). Due to haemolytic uraemic syndrome associated with a cumulative mitomycin-C dose of 40 mg/m² (10 mg/m² per course) the cumulative dose of mitomycin-C was reduced to 28 mg/m² (7 mg/m² per course). The 53 patients treated with the higher dose of mitomycin-C had a response rate of 61% compared to 45% for the 45 patients treated at the lower dose. This difference was not statistically significant. Further subgroup analysis was not performed as the study was not designed to have enough power to be analysed in such a way. After the mitomycin-C dose was reduced, careful surveillance for evidence of haemolysis was instituted and no further mitomycin-C given if haemolysis was observed. Although we reduced the dose of mitomycin-C, the higher dose of mitomycin-C may still be safely used if increased monitoring is instituted, but this needs to be investigated further. Mitomycin-C in combination with PVI 5-FU significantly improves response and failure-free survival but the optimal dose of mitomycin-C with respect to efficacy and toxicity requires clarification.

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Onycholysis in patients treated with docetaxel

We report two cases of onycholysis of the finger and toe nails following the application of docetaxel (100 mg/m²) given as single agent chemotherapy for metastatic breast cancer.

A 69-year-old female patient underwent lumpectomy and axillary lymph node dissection in October 1996. Histologic examination revealed breast cancer (ductal, NOS type, pT1c, G2) with two out of 14 lymph nodes positive. The patient received three cycles of a CMF therapy regimen postoperatively. In March 1997 the CMF therapy was interrupted, because liver ultrasound and X-ray examination revealed multiple metastases in the liver, spine, and osseous pelvis. Instead, a high dose adriamycin (100 mg/m²)-cyclophosphamide (600 mg/m²) combination chemotherapy was given over two cycles. Due to severe leukopenia, the chemotherapy regimen was changed again and docetaxel (100 mg/m²) was given in April 1997. A dose of 171 mg was administered over a one-hour infusion for three cycles every three weeks.

A 73-year-old female patient received neoadjuvant CMF chemotherapy for inflammatory breast cancer. After three cycles of treatment, radical mastectomy with axillary node dissection was performed in December 1996. Histologic examination revealed multicentric breast cancer (ductal, pT2, G2) with seven out of 16 lymph nodes positive. The patient received three cycles of a combination chemotherapy, containing 5-fluorouracil (1000 mg), cyclophosphamide (800 mg), and mitozantrone (10 mg/m²), at four-week intervals. During this treatment the patient developed multiple metastases in the liver